DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-318/S-002

Eli Lilly and Company
Attention: Sunita Zalani, Ph.D.
Regulatory Research Scientist, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Zalani:

Please refer to your supplemental new drug application (NDA) dated December 4, 2003, received December 5, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Forteo [teriparatide (rDNA origin)] Injection.

This "Changes Being Effected" supplemental new drug application provides for an updated Pen User Manual, Pen Carton, and Pen Label.

We have completed the review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (final printed labeling for the Pen User Manual, Pen Carton, and Pen Label submitted December 4, 2003).

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Orloff

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